**Exempt Research – Revised Common Rule (effective January 21, 2019)**

**Common Rule 45 CFR 46.104(d)**

**Exempt Categories:**

* Subpart B: Studies involving pregnant women, fetuses & neonates are eligible for exempt under all 8 categories
* Subpart C: Exemptions do not apply to research involving prisoners except “for research aimed at involving a broader subject population that only incidentally includes prisoners”
* Subpart D: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & exclusion of children in categories 2 & 3. For exempt categories 2.iii and 3.i.C the IRB conducts a limited IRB review to make the determinations required by §46.111(a)(7).
* Category 6 is the only category that applies to FDA-regulated research.
* Einstein is not implementing categories 7 & 8. If these categories are implemented, the IRB will conduct a limited IRB review to make the determinations required by §46.111(a)(8).

| **Category** | **New Citation** | **Exemption Category Description** | **Limited IRB Review** | **Conditions/Allowances/Limitations** |
| --- | --- | --- | --- | --- |
| 1 | **104(d)(1)** | **Research in established or commonly accepted education settings that involves normal educational practices** | N/A | Not likely to adversely impact students’ opportunity to learn or assessment of educatorsNote: Some research under this category may require the submission of consent documents and scripts.[[1]](#footnote-1) |
| 2 | **104(d)(2)** | **Research only includes educational tests, surveys, interviews, public observation if at least ONE of the following criteria is met:** |  N/A | Data collection only;May include visual or auditory recording;May NOT include interventions Note: Einstein requires submission of consent documents and scripts for this category.1 |
| 1. Recorded information cannot readily identify the subject (directly or indirectly/linked)
 |  N/A | Surveys & interviews: NO children**;** Educational tests or observation of public behavior: Can only include children when investigators do not participate in activities being observed |
| 1. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)
 |   N/A | Surveys & interviews: NO children; Educational tests or observation of public behavior: Can only include children when investigators do not participate in activities being observed |
| 1. Information is recorded with identifiers & IRB conducts Limited Review
 | Privacy and confidentiality review  | NO children |

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| --- | --- | --- | --- | --- |
| 3 | **104(d)(3)(i)** | **Research involving benign behavioral interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:** |   N/A | NO children; * May not include medical interventions;
* Data may only be collected through verbal or written responses (including data entry) or audiovisual recording
* Prospective consent required;
* No deception unless participant prospectively agrees to be deceived

BBI must be:* Brief in duration
* Painless/harmless
* Not physically invasive
* Not likely to have a significant adverse lasting impact on subjects
* Unlikely that subjects will find interventions offensive or embarrassing

 Note: Einstein requires submission of consent documents and scripts for this category.1 |
| 1. Recorded information cannot readily identify the subject (directly or indirectly/linked)
 |   N/A |
| 1. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)
 |   N/A |
| 1. Information is recorded with identifiers & IRB conducts Limited Review
 | Privacy and confidentiality review |
| 4 | **104(d)(4)** | **Secondary research for which consent is not required: Use of identifiable information or identifiable biospecimen that have been or will be collected for some other ‘primary’ or ‘initial’ activity, if ONE of following criteria met:** |   | No primary collection from subjects for the research; Allows both retrospective and prospective secondary use  |
| 1. Biospecimens or information is publicly available
 |   N/A | Must be publicly available  |
| 1. Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects
 |   N/A |  |
| 1. Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”
 |   N/A | HIPAA still applies; HIPAA protections include authorization or waiver of authorization; |
| 1. Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities
 |   N/A | If research generates identifiable private information it is subject to specified federal privacy laws (see Common Rule for list) |

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| --- | --- | --- | --- | --- |
| 5 | **104(d)(5)** | **Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.** |   N/A | Must be posted on a Federal Website  |
| 6 | **104(d)(6)** | **Taste and food quality**  |   N/A |   |
| 7 | **104(d)(7)** | **Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required**  | -Broad consent is obtained --Documented or documentation waived- If there is a change made for researchpurposes in the way material stored or maintained,Privacy and confidentiality review | **EINSTEIN IS NOT IMPLEMENTING**All requirements for broad consent must be met; MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses  |
| 8 | **104(d)(8)** | **Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required** | -Privacy and confidentiality review &-research is within the scope of the broad consent &-PI does not plan to return research results | **EINSTEIN IS NOT IMPLEMENTING**Privacy and confidentiality protections adequate; Broad consent was obtained**;**Documented or documentation waivedNo plan to return research results; MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses |

1. May include short oral scripts, cover letters, introductory paragraphs on surveys/research instruments and e-mails introducing potential research subjects to the study. [↑](#footnote-ref-1)